

902 KAR 20:145. Operations and services; rural health clinics.

RELATES TO: KRS 216B.010-216B.130, 216B.990(1), (2), 218A.175(1), 45 C.F.R. Part 160, Part 164, 42 U.S.C. Part 254r, 42 U.S.C. 1320d-2 – 1320d-8

STATUTORY AUTHORITY: KRS 216B.042(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042(1) requires the Kentucky Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes the minimum requirements for the operation of and services provided by rural health clinics.

Section 1. Location and Requirement to Provide Services. (1) A rural health clinic shall:

(a) Be located in:

1. A non-urbanized area, as determined by the United States Census Bureau; and
2. An area designated or certified by the Health Resources and Services Administration as

a:

- a. Health professional shortage area; or
- b. Medically-underserved area; and

(b) Comply with the requirements established in Sections 2 and 3 of this administrative regulation.

(2) A rural health clinic shall be:

- (a) Freestanding; or
- (b) A subordinate part of a licensed health facility or health service.

Section 2. Administration and Operation. (1) The licensee shall be legally responsible for the operation of the clinic and for compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the clinic.

(2) The rural health clinic shall be under the medical direction of a physician.

(3) The licensee shall:

- (a) Establish written policies and lines of authority; and
- (b) Designate an administrator who shall be principally responsible for the daily operation of the clinic.

(4) Patient care policies shall be developed by:

- (a) One (1) or more physicians;
- (b) One (1) or more advanced practice registered nurses or physician assistants; and
- (c) At least one (1) member who is not an employee of the rural health clinic.

(5) The policies shall include:

(a) A description of the services provided directly by the rural health clinic or through agreement;

(b) Guidelines for the medical management of health problems, including conditions that require medical consultation and patient referral;

(c) Procedures for maintaining health records;

(d) Procedures for the storage, handling, and administration of drugs and biologicals; and

(e) Procedures for an annual review and evaluation of services provided by the clinic.

(6) Personnel.

(a) The rural health clinic shall have:

1. At least one (1) physician;
2. At least one (1) advanced practice registered nurse or physician assistant; and

3. Other staff or ancillary personnel necessary to provide the services essential to the clinic's operation.

(b) The physician shall:

1. Be responsible for all medical aspects of the clinic and provide direct medical services in accordance with the Medical Practice Act, KRS Chapter 311;

2. Except in extraordinary circumstances, which shall be documented in the clinic's records, be physically present no less than once in every two (2) week period to provide medical direction, supervision, and consultation to the clinic's staff;

3. In conjunction with the advanced practice registered nurse or nurses, or physician assistant or assistants, participate in developing, executing, and reviewing the rural health clinic's written policies and services;

4. Review the rural health clinic's patient records;

5. Provide medical orders and medical care services to patients of the rural health clinic; and

6. Be available within one (1) hour, through direct telecommunication, for:

a. Consultation;

b. Assistance with medical emergencies; or

c. Patient referral.

(c) The advanced practice registered nurse or physician assistant shall:

1. Participate in the development, execution, and review of the written policies governing the services the rural health clinic provides;

2. Participate with the physician in review of patient health records; and

3. Provide services in accordance with rural health clinic policies and established protocols.

(d) If the practitioner is an advanced practice registered nurse, the nurse shall comply with:

1. The Nurse Practice Act, KRS Chapter 314; and

2. Administrative regulations relating to the practice of an advanced practice registered nurse, 201 KAR Chapter 20.

(e) If the practitioner is a physician assistant, the physician assistant shall comply with:

1. KRS 311.840 through 311.862; and

2. Administrative regulations relating to the practice of a physician assistant, 201 KAR 9:084.

(f) The advanced practice registered nurse or physician assistant shall perform the following functions, to the extent they are not performed by a physician:

1. Arrange for, or refer a patient to, needed services that are not provided at the rural health clinic; and

2. Assure that adequate patient health records are maintained and transferred if a patient is referred.

(7) The rural health clinic shall have a written linkage agreement or an arrangement for the referral of patients to receive the following services, if required:

(a) Inpatient hospital care;

(b) Physician services in a hospital, patient's home, or long term care facility;

(c) Additional and specialized diagnostic and laboratory services that are not available at the rural health clinic;

(d) Home health services;

(e) Services provided by a local health department;

(f) Emergency medical services; and

(g) Pharmacy services.

(8) Medical Records.

(a) The rural health clinic shall maintain patient records in accordance with written policies

and procedures.

(b) A member of the clinic's professional staff shall:

1. Be responsible for maintaining the records; and
2. Ensure that the records are:
 - a. Systematically organized;
 - b. Readily accessible; and
 - c. Accurately documented.

(9) For a patient receiving health care services, the rural health clinic shall maintain a record that includes the following as applicable:

- (a) Identification and social data;
- (b) Evidence of consent forms;
- (c) Pertinent medical history;
- (d) Assessment of the health status and health care needs of the patient;
- (e) A brief summary of the episode, disposition, and instructions to the patient for each contact;
- (f) Reports of physical examinations, diagnostic, and laboratory test results;
- (g) Consultative findings;
- (h) All orders, reports of treatments rendered, and medications given;
- (i) Pertinent information necessary to monitor the patient's progress; and
- (j) Signature of the physician or other health care practitioner on each order written or treatment provided.

(10) Records.

(a) Ownership.

1. Medical records shall be the property of the clinic.
2. The original medical record shall not be removed from the clinic except by court order.
3. Copies of a medical record or portions of the record may be used and disclosed. Use and disclosure shall be as established in this administrative regulation.

(b) Confidentiality and Security: Use and Disclosure.

1. The clinic shall maintain the confidentiality and security of medical records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, as amended, including the security requirements mandated by subparts A and C of 45 C.F.R. Part 164, or as provided by applicable federal or state law.

2. The clinic may use and disclose medical records. Use and disclosure shall be as established or required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation.

3. A clinic may establish higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164.

(c) Confidentiality of all patient records shall be maintained at all times.

(11) After the patient's death or discharge, the completed medical record shall be placed in an inactive file and retained for a minimum of six (6) years, or in the case of a minor, a minimum of three (3) years after the patient reaches the age of majority under state law, whichever is the longest.

(12) The rural health clinic shall:

- (a) Carry out or arrange for an annual evaluation of its total program;
- (b) Consider the findings of the evaluation; and
- (c) Take corrective action, if necessary.

(13) The evaluation shall include:

- (a) The utilization of clinic services, including at least the:

1. Number of patients served; and
2. Volume of services;
- (b) A representative sample of both active and closed clinical records; and
- (c) The rural health clinic's health care policies.

Section 3. Services. (1) The rural health clinic shall develop and maintain written protocols that shall:

- (a) Be signed by a staff physician;
- (b) Explicitly direct the step-by-step collection of subjective and objective medical data from a patient;
- (c) Direct explicit medical action depending on the medical data collected; and
- (d) Include:
 1. Standing orders;
 2. Rules of practice; and
 3. Medical directives.
- (2) The rural health clinic staff shall provide diagnostic and therapeutic services, and supplies commonly furnished:
 - (a) In a physician's office; or
 - (b) At the entry point into the health care delivery system.
- (3) Clinic services shall include:
 - (a) Medical history;
 - (b) Physical examination;
 - (c) Assessment of health status;
 - (d) Treatment for a variety of medical conditions;
 - (e) Basic laboratory services essential to the immediate diagnosis and treatment of the patient as described in this paragraph:
 1. Chemical examinations of urine by stick or tablet methods, or both, including urine ketones;
 2. Hemoglobin or hematocrit;
 3. Glucose;
 4. Examination of stool specimens for occult blood;
 5. Pregnancy tests; and
 6. Primary culturing for transmittal to a hospital laboratory or licensed laboratory; and
 - (f) Medical emergency procedures as a first response to common life-threatening injuries and acute illness.
- (4) A clinic shall have available the drugs and biologicals commonly used in lifesaving procedures, including:
 - (a) Analgesics;
 - (b) Local anesthetics;
 - (c) Antibiotics;
 - (d) Anticonvulsants;
 - (e) Antidotes;
 - (f) Emetics;
 - (g) Serums; and
 - (h) Toxoids.
- (5) A clinic shall not operate in the same manner as or otherwise provide services that are equivalent to the services provided by a pain management facility defined by KRS 218A.175(1).
- (6) A clinic shall post in a conspicuous area at the entrance, visible from the outside of the

clinic:

(a) The hours that emergency medical services will be available in the clinic; and

(b) Where emergency medical services not provided by the clinic can be obtained during and after the clinic's regular scheduled hours of operation. (8 Ky.R. 420; eff. 1-6-1982; Am. 16 Ky.R. 1010; eff. 1-12-1990; 21 Ky.R. 608; 1056; eff. 9-21-1994; 28 Ky.R. 715; 1149; eff. 10-17-2001; TAm eff. 3-11-2011; -- Amd 44 Ky.R. 1721, 2214; eff. 5-4-2018.)